

Application of Robert Getts
Serial No. 09/802,162 filed 3/8/2001
Response of 9/21/2006 to Office Action of 3/21/2006

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Amendments to the Drawings

The attached sheets of drawings include changes to Figures 1-3. Those sheets have been amended to annotate them with Sequence ID Numbers.

Attachment: Replacement Sheets (Figures 1-3)

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Remarks

Receipt is acknowledged of the Office Action of March 21, 2006 in the above-captioned matter. Reconsideration of the application and a three month extension of the time provided for a response are requested. The Commissioner is hereby authorized to charge Deposit Account 50-1604 for all amounts required in connection with the present application and response.

Objections to Specification

Further to the objection to the specification, a replacement sheet for page 17 is attached. Replacement drawings are enclosed as well. In the replacement drawings, the specified poly A and poly T sequences are enumerated with Sequence ID Numbers; however, the nucleotide sequences of the capture sequences are not listed therein as they can be Cy3 or Cy5 or another custom sequence, as explained in the specification.

A paper sequence listing is enclosed as well. To facilitate submission of a corresponding computer sequence listing, counsel inquires herein whether such a listing may be emailed to the Examiner or to the Patent Office (and if so, which email address should be utilized). It is also noted that the present submission includes no new matter, as the sequences herein were presented in the specification when the application was originally filed.

Rejections Under 35 U.S.C. §103(a)

In the Office Action, claims 1-26 and 39-42 were rejected under 35 U.S.C. §103(a) based on a combination of Dellinger et al. (U.S. Patent No. 5,853,993) with Nilsen et al. (U.S. Patent No. 5,487,973), and claims 35-38 were rejected under 35 U.S.C. §103(a) with the further addition of Jane (U.S. Patent No. 5,902,724). Reconsideration of the rejections is respectfully requested.

With respect to claims 1 and 18, those claims are directed to a method for detection and assay on a microarray. It is respectfully submitted that one of ordinary skill would not be inclined to combine Dellinger with Nilsen to design such a method, as the combination of Dellinger's homopolymer technique with Nilsen's dendrimer technique would not produce a particularly useful assay. For example, homopolymers can allow more than one signal molecule to bind, making the results

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unpredictable or difficult to interpret. Also, homopolymers are found over represented in the genome which can cause undue noise in the assay. These are the types of factors that one of ordinary skill would want to avoid in designing a method for detection on a microarray, not the type of approach one would want to pursue. One would not be inclined to combine teachings that would be expected to produce unpredictable results and high noise. Rather, the expectations of one of ordinary skill based on the cited references show that the claimed invention is not obvious and represents patentable invention.

With respect to claims 2 and 22, they are directed to the use of an RT primer – wherein the RT primer further includes the capture sequence. Specifically, a method is recited in which the cDNA reagents are formed by contacting mRNA with a quantity of a RT primer having the capture sequence, and with a reverse transcriptase, under conditions for initiating reverse transcription of the mRNA. This method is highly advantageous in that it automatically incorporates the capture sequence into the cDNAs during the very process of forming those cDNAs. *See e.g.*, Figure 1 of application.

As Applicant had previously stated in the Office Action Response of December 28, 2005, it is submitted that this method has not been shown in any of the art cited.

The Examiner's response thereto is unclear. For example, on page 9 of the Office Action, the Examiner cited to col. 3 lines 20-24 (it is assumed that the citations are to Dellinger, although no reference name was given). But that paragraph does not teach or suggest the elements recited in claims 2 and 22.

The Examiner also cited to col. 5 lines 4-14. However, later on in that very paragraph (col. 5 lines 14-22), Dellinger indicates that the homopolymer tailing methods he contemplates are by use of terminal transferase, or ligation PCR amplification and cloning, or chemical ligation. None of these statements refer to the specific reverse transcription method recited in the claims.

Likewise, the Examiner also cited to col. 6 lines 8-12. That citation is to measurement of the length of poly A tail by PCR amplification using an oligo(dT) anchor primer. That citation also does not appear to teach or suggest the method recited in the claim – a specific method for obtaining cDNA reagents from mRNA of a target sample by contacting the mRNA in a reverse transcription method in which the RT primer includes the capture sequence.

Nor is inherency relevant here. The particular elements of the claimed method are not expressly

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or inherently in the references. For an obviousness rejection, the combination of references must teach or suggest each and every element of the claim. *See e.g.*, M.P.F.P. §2143.03 (8th Ed., Aug. 2006 Revision).

In contrast to all of those citations, claims 2 and 22 recite a method in which the capture sequence is part of the RT primer so as to produce an efficient synthesis of the cDNA. This method is highly beneficial in that it automatically incorporates the capture sequence into the cDNA at the same time that the cDNA is formed (*see e.g.*, Figure 1 of the present application), and it is respectfully submitted that this method is also patentable.

With respect to the claims directed to multiple channel assays (claims 28, 30, 32, and 34), the Office Action maintained that the limitations upon which Applicant's arguments were based were not present in the claims. Accordingly, those claims have been amended to recite the limitation that the assays utilize at least three different capture sequences.

Accordingly, it is submitted that these claims are all patentable as well, since a combination of references which incorporates the homopolymeric tailing taught by Dellinger would only allow the use of two types of homopolymeric tails and not three. A tail of adenine bases would hybridize with thymines (or vice versa), and a tail of cytosines would hybridize with guanines (or vice versa), such that three channel analysis would not be possible.

With respect to the methods of claims 4, 19, and 24 that utilize a spin column, reconsideration of those rejections is likewise requested. A method is claimed in which the spin column is used to remove RT primer. That method is also not taught or suggested by the references.

With respect to claims 35-38, those claims recite the use of multiple bases and accordingly are contrary to the required homopolymeric regions of Dellinger. As those claims recite a limitation which is contrary to one of the main principles provided in Dellinger, it is respectfully submitted that they cannot be obvious based upon a combination of Dellinger with other references. As the Manual of Patent Examining Procedure sets forth, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *See e.g.*, M.P.F.P. §2143.01 VI (8th Ed., Aug. 2006 Revision).

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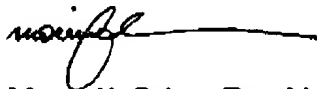
Applicant also maintains its request that the provisional double patenting rejections be withdrawn for the reasons set forth in the prior Office Action, or at minimum, that they be held in abeyance until arrival at agreement on allowable subject matter.

In the event that the Examiner is inclined to further maintain any of the rejections or issue any new ones, an interview at the Patent Office is requested.

In conclusion, as set forth in the remarks and claims set forth above, withdrawal of the pending rejections and allowance of all of the claims is respectfully requested.

Dated: September 21, 2006

Respectfully submitted,



Morris L. Cohen (Reg. No. 39,947)
1122 Coney Island Avenue, Suite 217
Brooklyn, New York 11230
(718) 859-8009 (telephone)
(718) 859-3044 (facsimile)